REMARKS

Objections

The Abstract was objected to, as being less than the required 50-150 words, and for allegedly not allowing the public to quickly determine the nature and gist of the technical disclosure or include what is new.

The Abstract has been amended to contain between 50-150 words, and includes additional detail regarding the invention. Therefore, the objection has been overcome and the Applicants respectfully request that the objection be withdrawn.

Priority

The priority of the present application was questioned in Paragraph 2 of the Official Action. However, the purpose of the objection was unclear to the Applicants, as the present case does not make a priority claim. In a telephone conference with the Examiner and the Applicants' attorney on Monday, December 3, 2007, the Examiner confirmed that the priority objection was made in error and should be disregarded. Therefore, the Applicants respectfully request that the objection be withdrawn.

Claim Status

Rejection Under 35 USC §112, Second Paragraph

Claim 11 is rejected under 35 USC §112, Second Paragraph as being indefinite. The Examiner asserts that the terms "improved" or "enhanced" are not specifically defined in the context of the Claim and that means for assessing said improvement is lacking. Therefore, the Examiner rejects the Claim for alleged failure to establish criteria for assessing improvement in stability of one particular embodiment over another.

The Applicants respectfully traverse the rejections. The preamble of Claim 11 has been amended to recite: "A method of providing a stable soft gelatin capsule...", thus removing the term "improving" and obviating the rejection. Therefore, the Applicants respectfully request withdrawal of the rejection.

Rejection Under 35 USC §112, First Paragraph

Claims 11-17 are rejected under 35 USC §112, First Paragraph because the specification allegedly does not reasonably provide enablement for the breadth of the Claims as recited. The Examiner asserts that the scope of the invention is very broad, encompassing every member of any of the subclasses recited in the Claims and specification. However, the Examiner asserts that there are only a few imprecisely described embodiments in the specification, and that the embodiments do not identify stability-conferring features of the various components. The Examiner further asserts that while the state of the art in pharmaceutical dosage formulation is well developed in terms of breadth of knowledge and methods for assessing stability, ... no artisan is expert in every type of compound or analytical technique. Therefore, the Examiner asserts that the specification does not enable one skilled in the art to employ the invention in a manner commensurate in scope with the Claims, and that it would not be possible, even for one skilled in the art to make and use the invention as claimed.

The Applicants respectfully traverse the rejection. As the Examiner notes, the test for enablement is whether one skilled in the art could make and use the claimed invention from the disclosures made in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics*, 8USPQ2d 1217 (Fed. Cir. 1988)).

The Applicants respectfully submit that one of skill in the art could make and use the claimed invention based on the disclosures made in the specification and information known in the art, without undue experimentation.

The specification, at page 4, beginning with line 31 discloses many non-limiting examples of active ingredients suitable for use as a highly concentrated pharmaceutical active. Page 5 continues with specific examples of compounds that are members of the listed subclasses of suitable pharmaceutical active compounds, and provides citation to a reference text. One of skill in the art therefore would indeed know what suitable pharmaceutical active compounds would be. Furthermore, five (5) specific example compositions, using four (4) different pharmaceutical active compounds, are provided in the table in the Examples section.

In the specification, at Page 6, beginning with line 17, specific examples of suitable stabilizing compounds are disclosed. Also, five (5) specific example compositions are provided in the table in the Examples section.

Finally, in the specification, at Page 7, beginning at line 4, specific examples of suitable solvents are disclosed. Citation to a reference text is also provided. In addition, five (5) specific example compositions are provided in the table in the Examples section.

Therefore, the Applicants respectfully submit that sufficient detail and precisely described embodiments are indeed provided in the specification. Furthermore, the Applicants submit that the level of skill of an artisan in the relevant art would be high, and that the examples and guidance (including citation to relevant reference books) provided by the Applicants would enable a skilled artisan to make and use the invention as claimed without undue experimentation. The Applicants therefore respectfully submit that the rejection has been overcome and respectfully request that the rejection be withdrawn.

Rejection Under 35 USC §102(b)

Claims 1-17 are rejected under 35 USC §102(b) as being anticipated by US Patent No. 5,569,466 to Tanner et al., ("Tanner"). The Examiner asserts that Tanner teaches a dosage unit form having a biologically active agent dissolved or suspended in a carrier liquid encapsulated in a soft elastic capsule, wherein the carrier liquid comprises at least about 20% maltitol syrup.

The Examiner asserts that the disclosure of Tanner is equivalent to the instantly claimed "pharmaceutical composition comprising...a suspended pharmaceutical active...encapsulated in a soft gelatin capsule". The Examiner equates maltitol to the claimed solvent. In addition, the Examiner asserts that "the suspended stabilizing agent of the instant claim is considered to be within the scope of Tanner on the basis of Tanner's claim of excipients". The Examiner further asserts that Tanner discloses pharmaceuticals.

The Applicants respectfully traverse the rejection. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

"Excipients" are disclosed in Tanner only as being generally known. Tanner does not disclose or name any particular excipients or any function they may have. Furthermore, Tanner specifically does not disclose the specific percentages and amounts of stabilizing agents as recited in the Claims. The Applicants, therefore, respectfully submit that

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Tanner does not disclose each and every element set forth in the Claims, and thus, as a matter of law, cannot anticipate the Claims. Therefore, the Applicants respectfully request that the rejection be withdrawn.

Conclusion

This response represents an earnest effort to place the present application in proper form and to overcome the objections and rejections. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of all pending claims are respectfully requested.

Respectfully submitted,

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